IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-95 (GMS)
CELLTRION, INC., CELLTRION HEALTHCARE, CO. LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH,	)	REDACTED - PUBLIC VERSION
Defendants.	)	

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS DEFENDANTS' COUNTERCLAIMS

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Originally Filed: July 17, 2018
Redacted Version Filed: July 24, 2018

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I. NATURE AND STAGE OF THE PROCEEDING

Genentech filed this patent infringement action on January 12, 2018.[1] On April 16, 2018, Celltrion moved to dismiss or stay it in favor of its own declaratory-judgment action in the Northern District of California, but Celltrion withdrew that motion after the California court dismissed its claims as statutorily barred. *See* D.I. 28; *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-276-JSW, 2018 WL 2448254, at *5-8 (N.D. Cal. May 9, 2018). Celltrion then answered Genentech's complaint in this case and asserted the same 65 declaratory-judgment claims that the California court had dismissed, this time as counterclaims. Genentech moved to dismiss those counterclaims, but, before briefing on that motion was complete, Celltrion filed an amended answer that still asserts 64 of the 65 counterclaims that were in its original answer and that were dismissed by the California court. Genentech again moves to dismiss all Celltrion's remaining counterclaims as statutorily barred. This is Genentech's opening brief in support of that motion.

II. SUMMARY OF ARGUMENT

This patent dispute arises from Celltrion's efforts to market a biosimilar of Herceptin®, a drug Genentech developed for the treatment of breast cancer. The regulatory approval scheme for biosimilars, contained in the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), sets forth a "carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement" that includes pre-litigation information exchanges and negotiations. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670-71 (2017). This scheme is commonly referred to as the "patent dance." *See id.*; *see also* 42 U.S.C. §§ 262(k)-(*l*).

[1] This brief refers to Defendants collectively as "Celltrion," to Plaintiffs collectively as "Genentech," and to individual parties by their full names or by abbreviations defined in the text.

Celltrion started but did not finish the patent dance. Rather than engage in the statutorily required negotiations to narrow the scope of the infringement litigation, 42 U.S.C. §§ 262(*l*)(4)-(6), Celltrion filed an anticipatory complaint in the Northern District of California seeking a declaration that 38 of the 40 patents Genentech identified during the parties' exchanges are either invalid or not infringed by its proposed product. *See Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-274-JSW (N.D. Cal.). Genentech filed this suit in response and moved to dismiss the California case because the BPCIA bars declaratory-judgment actions by biosimilar applicants that fail to complete their patent dance obligations. The California court agreed and dismissed Celltrion's complaint. *See Celltrion*, 2018 WL 2448254, at *5-8.

Celltrion refuses to give up on its statutorily barred declaratory-judgment claims, now raising them as counterclaims in this case. But they are barred here for the same reasons they were barred in California. Celltrion has purported to take steps over the past two weeks to resurrect the patent dance that it abandoned in January, but a biosimilar applicant cannot quit and then resume the patent dance at its unilateral discretion. And even if it could, Celltrion's recent actions cannot save its counterclaims, because Celltrion missed the BPCIA's deadlines by over four months. Celltrion's counterclaims should therefore be dismissed in their entirety under Federal Rule of Civil Procedure 12(b)(6).

III. STATEMENT OF FACTS

Herceptin® is a genetically engineered antibody that represents a profound breakthrough in the treatment of cancer. After the FDA approved Herceptin®, the scientific community hailed it as "the beginning of a whole new wave of biological drugs that modulate the causes of cancer" and as a sign that "the whole field of cancer research has turned a corner." D.I. 1, ¶ 4.

Herceptin® has transformed the treatment of breast cancer and has become the standard of care for its patient population.

Celltrion has submitted an Abbreviated Biologics License Application ("aBLA") seeking FDA approval to market a "biosimilar" of Herceptin® called Herzuma. *See* D.I. 36, Countercl. ¶ 15. A biosimilar is a drug that is similar enough to the innovator product (here, Herceptin®) that the FDA will allow the biosimilar applicant to piggyback on the innovator's clinical trials during the approval process. Celltrion and its marketing partner, Teva, hope to sell their biosimilar to the same patients who would otherwise be prescribed Genentech's Herceptin®. *See* D.I. 1, ¶ 21.

Although the filing of an aBLA is a technical act of patent infringement, the BPCIA directs the parties to engage in a series of exchanges and negotiation before any litigation commences. *See* 35 U.S.C. § 271(e)(2); 42 U.S.C. §§ 262(k)-(*l*); *see also Genentech, Inc. v. Amgen Inc.*, No. 17-1407-GMS, 2018 WL 503253, at *1-2 (D. Del. Jan. 22, 2018). These exchanges, known informally as the "patent dance," are designed to narrow disputes over infringement, in part by ensuring the "reference product sponsor" (here, Genentech) has received enough information from the biosimilar applicant to be able to narrow the patents to be asserted before filing suit. *See Sandoz*, 137 S. Ct. at 1670-71. The exchanges are governed by a series of statutory subsections in 42 U.S.C. § 262(*l*).

After the FDA accepted Celltrion's aBLA for filing on July 28, 2017, Genentech and Celltrion began the patent dance in an effort to narrow the patents that would be at issue in the litigation everyone knew was coming. D.I. 36, Countercl. ¶ 17. Pursuant to 42 U.S.C. § 262(*l*)(3)(A), on October 10, 2017, Genentech served a list of 40 patents that it believed could reasonably be asserted if Celltrion made, used, imported, or offered to sell Herzuma in the

United States ("Genentech's 3A List"). *See id.* ¶ 19; Ex. 1.[2] Celltrion continued to participate in the patent dance and served its response under § 262(*l*)(3)(B)(ii) on November 7, 2017 ("Celltrion's 3B Statement"). *See* D.I. 36, Countercl. ¶ 59; Ex. 2. Celltrion provided no response to two of the patents on Genentech's 3A List, U.S. Patent Nos. 6,242,177 and 6,121,428, but stated that it did not intend to begin commercial marketing of its biosimilar product before they would expire. *See* Ex. 2 at 1. As to the remaining 38 patents, Celltrion provided non-infringement, invalidity, or unenforceability contentions. *See* D.I. 1, ¶ 33. Genentech provided responsive contentions on January 5, 2018, pursuant to § 262(*l*)(3)(C) ("Genentech's 3C Statement"), narrowing its focus to 18 of the original 40 patents based on representations in Celltrion's 3B Statement about, for example, Celltrion's manufacturing processes. *See* D.I. 36, Countercl. ¶ 62; Ex. 3.

With its 3C Statement, Genentech also started the negotiations required by § 262(*l*)(4) about the scope of the infringement case to be filed by Genentech. *See* D.I. 36, Countercl. ¶ 63. Genentech proposed that the parties litigate the 18 patents for which it provided contentions with its 3C Statement. *See id.*; Ex. 3. Celltrion responded on January 11, 2018, expressing its desire to litigate all 40 patents on Genentech's 3A List.[3] *See* D.I. 36, Countercl. ¶ 64; Ex. 4. Celltrion also provided notice under 42 U.S.C. § 262(*l*)(8)(A) that it might begin commercially marketing its Herzuma product after 180 days, i.e., on July 10, 2018. *Id.* Countercl. ¶ 65.

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[2] "Ex." refers to the exhibits to the Declaration of Andrew J. Danford filed with this brief.

[3] Celltrion appears to take no position on the date the parties' negotiations under § 262(*l*)(4) began, but it alleges that they began no later than January 11, 2018. *See* D.I. 36, Countercl. ¶ 64 ("On January 11, 2018, Celltrion, Inc. wrote to Genentech in response to its 3(C) Statement. Celltrion, Inc. stated that, pursuant to 42 U.S.C. § 262(l)(4)(A), Celltrion, Inc. wished to litigate all of the patents on Genentech's 3(A) List.").

Because Genentech and Celltrion disagreed on the proper scope of a first-phase patent case, the BPCIA contemplated that they would continue to "engage in good faith negotiations." 42 U.S.C. § 262(*l*)(4)(A). But "[i]f, within 15 days of beginning negotiations," Genentech and Celltrion still could not agree, the BPCIA held that "the provisions of [§ 262(*l*)(5)] shall apply to the parties." *Id.* § 262(*l*)(4)(B). Section 262(*l*)(5) provides for an exchange of patent lists to determine the scope of the immediate infringement action. *Id.*

Celltrion did not engage in those good-faith negotiations. Instead, it filed a lawsuit in the U.S. District Court for the Northern District of California seeking declaratory judgment of non-infringement and/or invalidity for each of the 38 patents addressed in its 3B Statement, a mere 20 minutes after making its opening offer. *See* D.I. 1, *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-274-JSW (N.D. Cal. filed Jan. 11, 2018).

Celltrion plainly had abandoned the patent dance. So, the next day, Genentech filed this case alleging infringement of all 40 of the patents on Genentech's 3A List. D.I. 1. Genentech filed suit here, because this Court was already presiding over litigation between Genentech and two other companies about the validity and scope of many of the same patents at issue in this case.[4]

Genentech moved to dismiss Celltrion's California complaint[5] because, among other things, Celltrion's failure to complete the patent dance caused its declaratory-judgment action to

[4] *See Genentech, Inc. v. Amgen, Inc.*, No. 17-1407-GMS (D. Del.) (involving claims against Amgen's biosimilar version of Genentech's Avastin® biologic drug); *Genentech, Inc. v. Amgen, Inc.*, No. 17-1471-GMS (D. Del.) (same); *Genentech, Inc. v. Pfizer Inc.*, No. 17-1672-GMS (D. Del.) (involving claims against Pfizer's biosimilar version of Herceptin®).

[5] Celltrion filed an amended complaint in California shortly after filing its initial complaint. *See* D.I. 39-5, *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-274-JSW (N.D. Cal. filed Feb. 8, 2018). For simplicity, this brief refers to Celltrion's first amended complaint as its complaint.

be statutorily prohibited by the BPCIA. *See* 42 U.S.C. § 262(*l*)(9)(B). The California court agreed and, on May 9, 2018, dismissed Celltrion's complaint because "Celltrion was obligated to complete all required procedures [under the patent dance] before filing this lawsuit, and it did not." *Celltrion*, 2018 WL 2448254 at *7. The court rejected Celltrion's arguments that it had complied with the statute. *Id.* at *5-8. The court also allowed Celltrion "leave to amend, to the extent that the identified deficiencies can be corrected consistent with counsels' obligations under Federal Rule of Civil Procedure 11," *id.*, but Celltrion filed a notice that it would not do so. Ex. 5. Final judgment was entered on June 11, 2018, Ex. 6, and Celltrion has appealed.

Celltrion moved to dismiss this case in favor of the California case but withdrew that motion when the California case was dismissed. D.I. 28. At the same time Celltrion withdrew its motion, it filed an answer and counterclaims seeking declaratory judgments of non-infringement, invalidity, or unenforceability for 38 of the 40 patents at issue in this case. D.I. 29. Genentech moved to dismiss those counterclaims, D.I. 31, but, in lieu of opposing Genentech's motion, Celltrion filed an amended answer and counterclaims dropping its unenforceability arguments, D.I. 36. Celltrion's current counterclaims are virtually identical to the declaratory-judgment claims that the California court dismissed as statutorily barred. *See* Ex. 7 (redline comparing substantive portions of D.I. 36, Amended Counterclaims, to substantive portions of Celltrion's California complaint, D.I. 39-5, *Celltrion, Inc. v. Genentech, Inc.*, C.A. No. 4:18-cv-274-JSW (N.D. Cal. filed Feb. 8, 2018)).

Apparently recognizing this problem, Celltrion attempted to resurrect the patent dance this June—months after the statutory deadlines for it to act had passed. On June 6, 2018, Celltrion sent Genentech a letter purporting to contain its 5A Number. D.I. 36, Countercl. ¶ 67. Five days later, Celltrion wrote to Genentech again, this time purporting to send its 5B List. *Id.*

at Countercl. ¶ 68. Genentech objected to Celltrion's belated attempt to resurrect the patent dance and recapture statutory benefits that it had long ago forfeited by failing to meet the BPCIA's deadlines; but, out of an abundance of caution, Genentech also provided its own list (mirroring its claims in this case). *Id.* Countercl. ¶ 69. Also out of an abundance of caution, Genentech filed an additional suit against Celltrion, which Genentech would have been required to do if Celltrion had complied with the patent dance. *See Genentech, Inc. v. Celltrion, Inc.*, C.A. No. 18-1025 (D. Del. filed July 11, 2018). Genentech will seek to have that second lawsuit consolidated with this case. *See* D.I. 39 (explaining the statutory uncertainty that prompted Genentech to file its second complaint).

IV. ARGUMENT

A. Legal Standard

"To survive a motion to dismiss" under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Rule 12(b)(6) authorizes a court to dismiss a claim on the basis of a dispositive issue of law," including lack of a statutory remedy. *See Seismic Reservoir 2020, Inc. v. Paulsson*, 785 F.3d 330, 335 (9th Cir. 2015); *see also Neitzke v. Williams*, 490 U.S. 319, 326 (1989) (holding that "a claim must be dismissed" if "as a matter of law it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations"); *Eisai Co., Ltd. v. Mutual Pharm. Co., Inc.*, No. 06-3613-HAA, 2007 WL 4556958, at *8-12 (D.N.J. Dec. 20, 2007) (dismissing claim under Rule 12(b)(6) for failure to comply with the Hatch-Waxman Act).

B. Celltrion's declaratory-judgment counterclaims are barred by the BPCIA because Celltrion did not complete required steps in the patent dance.

This is the second action in which Celltrion has sought a declaratory judgment of non-infringement, invalidity, or unenforceability of the patents-in-suit. Celltrion first asserted these claims in the Northern District of California, but the California court dismissed them last month as statutorily barred by the BPCIA because Celltrion had failed to comply with the BPCIA's patent dance procedure. Celltrion repudiated the patent dance when it filed its California complaint in January; it cannot undo that repudiation now. And even if it could, because the time limits for Celltrion to act under the BPCIA expired long ago, Celltrion cannot remedy the deficiencies that plagued its California claims. Each of Celltrion's declaratory-judgment counterclaims (i.e., counterclaims I-LXIV) should, therefore be dismissed for failure to state a claim under Rule 12(b)(6).

1. *The BPCIA establishes a system of incentives and penalties to narrow the scope of biosimilar patent litigation.*

The BPCIA embodies a compromise. Biosimilar manufacturers are spared the tremendous expense of replicating the clinical trials that innovator companies must conduct to obtain regulatory approval. In return, the innovator companies obtain early, pre-litigation access to information needed to identify and narrow patent disputes, and some control over the timing and location of that litigation. As the Supreme Court summarized it last year, the BPCIA "sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement." *Sandoz*, 137 S. Ct. at 1670.

"To encourage parties to comply with its procedural requirements, the BPCIA includes various consequences for failing to do so." *Id.* at 1672. Section 262(*l*)(9) ensures that litigation will be orderly by restricting a biosimilar applicant's ability to bring claims outside the BPCIA

framework. For example, to encourage the biosimilar applicant to start the patent dance, the applicant forfeits any right to seek declaratory relief unless it produces its aBLA and the other manufacturing information required by Section 262(*l*)(2)(A). *See* 42 U.S.C. § 262(*l*)(9)(C); *see also Sandoz*, 137 S. Ct. at 1672.

If the biosimilar applicant makes the disclosures required under Section 262(*l*)(2)(A), the BPCIA directs the parties to undertake the series of exchanges contemplated by the patent dance, culminating with an infringement complaint filed by the reference product sponsor (here, Genentech). This is the "first phase" of litigation under the BPCIA. *See Sandoz*, 137 S. Ct. at 1671-72. As an incentive to keep the patent dance exchanges on track, the BPCIA strips the biosimilar applicant of the ability to seek a declaratory judgment for any patent included on the initial list of relevant patents provided by the reference product sponsor (i.e., the sponsor's 3A List) if the applicant fails to complete certain steps of the patent dance. *See* 42 U.S.C. § 262(*l*)(9)(B) ("If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action . . . for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A) . . . ."); *see also Sandoz*, 137 S. Ct. at 1672.

2. *Celltrion's counterclaims are barred by 42 U.S.C. § 262(l)(9)(B) because Celltrion did not complete the patent dance.*

Celltrion's counterclaims for declaratory relief are barred under Section 262(*l*)(9)(B) because Celltrion did not complete the patent dance. Once Genentech served its 3C Statement on January 5, 2018, the BPCIA required Celltrion to initiate "good faith negotiations" over the scope of the first phase of litigation. *See* 42 U.S.C. § 262(*l*)(4)(A); *Celltrion*, 2018 WL 2448254, at *2 ("Following the exchange of the 3(A), (B), and (C) Disclosures, the applicant and the

reference product sponsor must engage in 'good faith negotiations' to reach an agreement identifying which patents will be the subject of 'immediate' patent infringement litigation."). If the parties had agreed on a list of patents, Genentech would have been required to "bring an action for patent infringement with respect to each such patent." 42 U.S.C. §§ 262(*l*)(4)(A), (6)(A). But if the parties could not reach agreement within 15 days of beginning negotiations, "the express terms of the BPCIA required both Celltrion and Genentech to complete the steps outlined in Section (*l*)(5)." *Celltrion*, 2018 WL 2448254, at *5; 42 U.S.C. § 262(*l*)(4)(B). Section 262(*l*)(5) required Celltrion to select and notify Genentech of "the number of patents" to be litigated (i.e., its "5A Number"), *id.* at *2, *5; 42 U.S.C. § 262(*l*)(5)(A), and, within five days of that notice, exchange lists of "Phase I" patents with Genentech (i.e., its "5B List"), *id.* 42 U.S.C. § 262(*l*)(5)(B)(i).

That is how the process should have unfolded. But after receiving Genentech's contentions and opening offer, Celltrion refused to negotiate. Celltrion sent a counteroffer and filed a complaint in California the same day. *Celltrion*, 2018 WL 2448254, at *3; Ex. 4.

The California court concluded that Celltrion's claims were barred by § 262(*l*)(9)(B) "[b]ecause Celltrion did not complete its obligations under Section (*l*)(5)." *Celltrion*, 2018 WL 2448254, at *5. "Celltrion fail[ed] to allege . . . that it provided Genentech with its 5(A) Number or simultaneously exchanged 5(B) lists with Genentech." *Id.* "In these circumstances," the court held, "the BPCIA is clear: Celltrion may not bring a declaratory-judgment action with respect to any patent on Genentech's [3A List]." *Id.* The court then dismissed Celltrion's complaint for failure to state a claim. *Id.* at *8.

Celltrion's counterclaims in this case include virtually the same factual allegations, counts, and requests for relief as Celltrion's California complaint. Exhibit 7 is a redline

comparison of the substantive elements of Celltrion's counterclaims in this case against the substantive elements of Celltrion's California complaint.[6] There are no material differences. Both pleadings seek declaratory judgments of invalidity, non-infringement, or unenforceability of 38 patents; both assert 65 counts (with the same titles and in the same order); and both include a substantively identical description of the parties' patent dance. And—significantly for this motion—"Celltrion never alleges," in either complaint, "that it either (i) sent its 5(A) Number to Genentech, or (ii) that the parties simultaneously exchanged 5(B) lists" during the patent dance. *Celltrion*, 2018 WL 2448254, at *5. That was dispositive of Celltrion's claims for declaratory relief in California, and it should be dispositive of Celltrion's claims for declaratory relief here.

The only difference between Celltrion's now-dismissed California claims and its counterclaims here is the type of pleading in which they were raised. That is immaterial. As the Supreme Court explained, the BPCIA's declaratory-judgment bars are intended to "encourage parties to comply with [the BPCIA's] procedural requirements" and to provide "consequences for failing to do so." *Sandoz*, 137 S. Ct. at 1672. If a biosimilar applicant starts but refuses to finish the patent dance, one of those consequences is that "the [reference product sponsor], but not the applicant, [may] seek declaratory relief with respect to infringement, validity, or enforceability" of the patents on the sponsor's 3A List. *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1322 (Fed. Cir. 2017). Celltrion's counterclaims seek the same declaratory relief as its California complaint, so Celltrion's counterclaims should be deemed statutorily barred and dismissed.

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[6] To facilitate this comparison, Exhibit 7 omits non-substantive sections, like the introduction, description of the parties, jurisdiction and venue allegations, and description of the statutory scheme. Genentech does not believe these sections are relevant to this motion; but, for completeness, Exhibit 8 is a comparison of Celltrion's entire counterclaims against its entire complaint in the California Action.

Any other outcome would allow Celltrion to have its cake and eat it too. If counterclaims are not subject to the BPCIA's declaratory-judgment bars, a biosimilar applicant could engage in the patent dance through the contention exchanges (i.e., the 3B and 3C Statements), abandon the dance, and still exercise the unilateral ability to increase the scope of the infringement action through declaratory-judgment counterclaims after it is sued. But the right to exercise some control over the scope of the infringement action is one that a biosimilar applicant earns by complying with the patent dance (e.g., § 262(*l*)(5)(A) allows the applicant to name the number of patents for the first-phase infringement action). Celltrion is attempting to exercise that right without having earned it.

Celltrion will no doubt argue that it should be allowed to maintain its counterclaims so it can get certainty on both infringement and validity of all of the patents on Genentech's 3A List before it launches Herzuma, even if Genentech does not elect to pursue all of those patents through judgment. In a typical patent case, that argument may have merit. *See, e.g.*, 6 Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 1406 (3d ed. Apr. 2018 update) (noting that standard practice allows declaratory-judgment counterclaims in infringement cases). But this is not a typical patent case—it is part of Congress's "carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement" for biosimilar drugs. *Sandoz*, 137 S. Ct. at 1670. The BPCIA's declaratory-judgment bars can only be effective at "reinforc[ing] the applicant's incentives to complete the orderly process" set out in the scheme if they have teeth. *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1057 (Fed. Cir. 2016). Celltrion knowingly and willfully abandoned the patent dance, creating litigation on opposite coasts, increasing the costs for the parties, and delaying resolution of this dispute. Section 262(*l*)(9)(B)

prescribes the penalty for Celltrion's gamesmanship, and—as the California court has already found—it is the loss of Celltrion's ability to seek declaratory relief.

3. *Celltrion's attempt to resurrect the patent dance after abandoning it for over four months cannot save its statutorily barred declaratory-judgment counterclaims.*

Celltrion's recent attempt to resurrect the patent dance, presumably in an effort to cure the deficiencies that doomed its California claims, fails to save its counterclaims. By the time Celltrion purported to provide its 5A Number, at least 146 days had passed since the parties started their negotiations under 42 U.S.C. § 262(*l*)(4). That is far more than the 15 days contemplated by the statute, 42 U.S.C. § 262(*l*)(4)(B), which expired no later than January 26, 2018.[7] As the California court explained, "[a]t th[at] juncture, the express terms of the BPCIA required both Celltrion and Genentech to complete the steps outlined in Section (*l*)(5)." *Celltrion*, 2018 WL 2448254, at *5. But Celltrion did not complete those steps at that juncture. Celltrion permanently abandoned the patent dance in January, and it cannot resurrect it by attempting to cure its failure to act retroactively, let alone over four months later.

The BPCIA does not contemplate an indefinite gap between the parties' negotiations under § 262(*l*)(4) and the list-exchange procedures in § 262(*l*)(5). Section 262(*l*)(4) establishes a clear window for the parties' negotiations: "If, ***within 15 days of beginning negotiations***[, the parties] fail to agree on a final and complete list of [patents for the first-phase infringement suit], the provisions of ***paragraph (5) shall apply*** to the parties." 42 U.S.C. § 262(*l*)(4)(B) (emphasis added). Section 262(*l*)(5)(A) follows with its own command: "The subsection (k) applicant ***shall notify*** the reference product sponsor of the number of patents that such applicant will provide to

[7] This assumes the parties' § 262(*l*)(4) negotiations began on January 11, 2018, a date that Celltrion alleges they were ongoing. D.I. 36, Countercl. ¶ 64. Genentech maintains that the negotiations began on January 5, 2018, which would create a 152-day gap.

the reference product sponsor under subparagraph (B)(i)(I)." Nothing in these mandatory provisions contemplates a months-long hiatus.[8]

It is a bedrock principle of statutory interpretation that courts "should favor an interpretation that gives meaning to each statutory provision." *Life Techs. Corp. v. Promega Corp.*, 137 S. Ct. 734, 740 (2017); *see also Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1654 (2017) (noting that under the "surplusage canon," there is a "presumption that each word Congress uses is there for a reason"). But any reading of the BPCIA that would allow Celltrion to resurrect the patent dance months after abandoning the parties' § 262(*l*)(4) negotiations would render the 15-day window in § 262(*l*)(4)(B) meaningless. Parties would be free to drag out the negotiations as long as they would like, effectively stalling the "orderly process" that Congress created. *Amgen*, 827 F.3d at 1057. To avoid distorting the BPCIA's text and frustrating its goals, Celltrion's belated attempt to excuse its noncompliance should be rejected and its counterclaims should be dismissed.

V. CONCLUSION

Genentech respectfully requests that the Court dismiss each of Celltrion's Counterclaims.

[8] Celltrion's own actions signal its lack of faith in this theory. Despite being given leave to amend the complaint in its favored forum (California) "to the extent that the identified deficiencies can be corrected consistent with counsels' obligations under Federal Rule of Civil Procedure 11," *Celltrion*, 2018 WL 2448254 at *8, Celltrion filed a notice that it would not amend on June 8—***two days after*** purporting to reopen the patent dance. *See* Ex. 5.

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CERTIFICATE OF SERVICE

I hereby certify that on July 24, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on July 24, 2018, upon the following at the email addresses indicated below:

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